UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,911	10/11/2000	C. Alexander Turner JR.	LEX-0068-USA	9082

7590 09/24/2002

LANCE K. ISHIMOTO
LEXICON GENETICS INCORPORATED
4000 RESEARCH FOREST DRIVE
THE WOODLANDS, TX 77381

EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/24/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/689,911	Applicant(s) TURNER ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 08 July 2002 (Paper No. 12) has been entered in full. Claims 1-2 and 4 are amended and claims 5-8 are added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objections to the declaration at pg 2 of the previous Office Action (Paper No. 11, 01 April 2002) are *withdrawn* in view of the supplemental declaration (Paper No. 13, 08 July 2002). See section on Oath/Declaration, below.

2. The objections to the specification at pg 2 of the previous Office Action (Paper No. 11, 01 April 2002) are *withdrawn in part* in view of the amended title (Paper No. 12, 08 July 2002). Please see section on Specification, below.

3. The rejections to claims 1-4 under 35 U.S.C. § 112, first paragraph for enablement and written description, as set forth at pg 6-10 of the previous Office Action (Paper No. 11, 01 April 2002) are *withdrawn in part* in view of the amended claims (Paper No. 12, 08 July 2002). Please see section on 35 U.S.C. 112, first paragraph, below.

4. The rejections to claims 1-2 and 4 under 35 U.S.C. 112, second paragraph, as set forth at pg 10-11 of the previous Office Action (Paper No. 11, 01 April 2002) are *withdrawn in part* in view of the amended claims (Paper No. 12, 08 July 2002). Please see section on 35 U.S.C. 112, second paragraph below.

5. The rejections to claims 1 and 4under 35 U.S.C. 102(a), as set forth at pg 11-12 of the previous Office Action (Paper No. 11, 01 April 2002) are *withdrawn* in view of the amended claims (Paper No. 12, 08 July 2002).

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

7. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for originally filed claims 1-4 at pg 3-6 of the previous Office Action (Paper No. 11, 01 April 2002).

Specifically, claims 1-8 are directed to an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2 and an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino

acid sequence from amino acid number 33 to amino acid number 141 of SEQ ID NO: 2. The claims also recite recombinant expression vectors and a host cell comprising the expression vector.

Applicant's arguments (Paper No. 12, 08 July 2002), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Applicant asserts that even if further research might be required in certain aspects of the present invention, this does not preclude a finding that the invention has utility, as set forth by the Federal Circuit's holding in *In re Brana* (34 USPQ2d 1436 (Fed. Circ. 1995), which clearly states that "pharmaceutical inventions, necessarily includes the expectation of further research and development". Applicant argues that in assessing the question of whether undue experimentation would be required to practice the claimed invention, the key term is "undue" not "experimentation". Applicant contends that the need for some experimentation does render the claimed invention unpatentable and a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the polynucleotide and polypeptide of the instant application (SEQ ID NOs: 1 and 2, respectively) are not supported by either a credible, specific and substantial ("real-world") asserted utility or a well established utility. The polynucleotide and polypeptide do not have a substantial utility because basic research is required to study the properties and activity of the claimed polynucleotide that encodes the polypeptide of SEQ ID NO: 2. The specification of the instant application does not disclose the function of the polynucleotide and polypeptide and

only recites prophetic examples of how the claimed polynucleotide and polypeptide can be utilized in various assays (pg 2-3 and 8-10). Furthermore, the fact patterns of some of the cases cited by the Applicant and of the instant rejection are significantly different, and the court decisions are not binding with regard to the instant rejections. Although, as discussed *in re Brana*, that pharmaceutical inventions necessarily include further research and development, it is clear from the instant specification that the polypeptide described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this DNA and protein, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to

be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

(ii) Applicant asserts that the present invention has a number of substantial and credible utilities, not the least of which is in expanding the utility of data coming from the human genome project. Applicant argues that persons of skill in the art, as well as thousands of venture capitalists and investors recognize the utility, both scientific and commercial, of genomic data in general. Applicant submits that the usefulness of human genomic data, such as the presently claimed nucleic acids, is substantial and credible (worthy of billions of dollars and the creation of numerous companies) and well-established (the utility of human genomic information has been clearly understood for many years.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, commercial success of genomic data is not necessarily evidence of patentable utility. Commercial success requires more than the mere sale of a compound or the creation of a company. Commercial success is discussed in the MPEP at 716.03 and appears to be applicable to obviousness rejections, but does not appear to be a valid consideration for utility which requires specific, substantial and credible utility. Applicant also has not established a nexus between the *claimed* invention and evidence of commercial success.

(iii) Applicant contends that the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips. Applicant indicates that such "DNA chips" have utility as evidenced by hundreds of issued U.S. patents, such as U.S. Patent Nos. 5,445,934; 5,556,752;5,744,305; 5,837,832; 6,156,501; 6,261,776. Applicant asserts that the present nucleotide sequences are clearly related to human galanins, as detailed in the

specification. Applicant also argues that the specification teaches that galanins are associated with a wide variety of cellular functions and therefore, since the present sequences are specific markers of the human genome and such specific markers are targets for the discovery of drugs that are associated with human diseases and conditions associated with galanins, those of skill in the art would instantly recognize that the present nucleotide sequences would be an ideal, novel candidate for assessing gene expression using DNA chips.

Applicant's arguments have been fully considered but are not found to be persuasive. The asserted utility of assessing gene expression via DNA chips with the claimed polynucleotides is credible but not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose any specific nucleic acid sequences used to generate the gene chip. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Furthermore, although Applicant asserts that the polypeptide encoded by the claimed nucleic acid molecule is homologous to existing galanin proteins, the specification does not disclose any methods or working examples that demonstrate the polynucleotide and polypeptide of the instant application exhibit similar activities of other galanins, particularly human. The skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application as a galanin. Additionally, the specification of the instant application does not teach the skilled artisan which domains of the polypeptide of the instant application are structurally characteristic of galanins. One skilled in the art would not know the utility and function of the polypeptide of SEQ ID NO: 2, even if it was a putative galanin protein because, as discussed in the Applicant's response of 08 July 2002 (Paper No. 12) and related art, "galanin is widely distributed in the

central and peripheral nervous system where it exhibits a variety of physiological effects (PG 331; Floren et al. Neuropeptides 34(6): 3331-337, 2000) and neither the specification nor the prior art provides for the physiological significance of the disclosed and claimed polypeptide.

Therefore, the regulation and sequestration of the claimed polynucleotide (SEQ ID NO: 1) of the instant application, is not well characterized and one skilled in the art the art would not find the utility of the polynucleotide and polypeptide to be well-established, well-known or obvious.

(iv) Applicant asserts that the present nucleotide sequence has a specific utility in mapping the protein encoding regions of the corresponding human chromosome. Applicant argues that the present polynucleotide provides exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the given polynucleotide, a utility not shared by any other nucleic acid sequences. Applicant submits that the skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human chromosome.

Applicant's arguments have been fully considered but are not found to be persuasive. The asserted utility of chromosome mapping is credible but not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose a specific DNA target. The specification also does not teach what human chromosome or what region of the chromosome contains the nucleotide sequence of SEQ ID NO: 1 claimed in the instant application. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

(v) Applicant indicates that the requirements set forth in the Action for compliance with 35 U.S.C. § 101 do not comply with the requirements set forth by the PTO itself for compliance with 35 U.S.C. § 101. Applicant asserts that the PTO has issued numerous patents on polynucleotide sequences that have not been directly shown to be associated with the function of the protein that is set forth in the specification, or a direct association between the claimed sequences and a particular disease or condition. Applicant cites U.S. Patent Nos. 5,817,479, 5,654,173, 5,552,812, and 6,340,583 and states that none of these issued patents contain examples of the "real-world" utilities the Examiner requires.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the current rejection is in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial ("real world") utility. Additionally, each Patent Application is examined on its own merits. The invention that was deemed allowable in one patent has no bearing on this application.

8. Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth for claims 1 and 4 at pg 6 of the previous Office Action (Paper No. 11, 01 April 2002).

Applicant's arguments (Paper No. 2, 08 July 2002) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the above-mentioned reasons.

Applicant argues that the concerns for 35 USC §112, first paragraph have been addressed in the arguments made for 35 USC §101.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, since Applicant has not provided evidence to demonstrate that the claimed nucleic acid molecules have a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

35 USC § 112, second paragraph

9. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 2 is rejected as being indefinite. Stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification also does not provide an unambiguous definition for the term. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of **A** X SSC and **B** % SDS at **C**°C"), claim 2 fails to define the metes and bounds of the varying structures of nucleotide sequences recited in the claimed methods. The basis for this rejection is set forth at pg 11 of the previous Office Action (Paper No. 11, 01 April 2002).

Applicant's arguments (Paper No. 12, 08 July 2002), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that a claim need not describe the invention, such description being the role of the disclosure. Applicant submits that as a number of stringent hybridization conditions are defined in the specification and would be known to those of skill in the art. Applicant has

amended claim 2 to recite the phrase "highly stringent hybridization conditions". Applicant's arguments have been fully considered but are not found to be persuasive because it is inappropriate to read limitations in the specification into the claims. The claims must independently define the invention for which patent protection is sought. Therefore, the claims are still rejected as being indefinite because the claims do not recite a single set of conditions as stringent.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
September 12, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER